UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

UNITED STATES OF AMERICA,	)	**FILED UNDER SEAL**
	)	
Plaintiff,	)	**CR. No.** 2:25cr20032-JTF
	)	
v.	)	**18 U.S.C. § 2**
	)	**18 U.S.C. § 1347**
SANJEEV KUMAR,	)	**18 U.S.C. § 2422(a)**
	)	**21 U.S.C. § 331(k)**
Defendant.	)	

I N D I C T M E N T

THE GRAND JURY CHARGES:

OVERVIEW

1. During times material to this Indictment SANJEEV KUMAR ("KUMAR") was a licensed Tennessee physician (license no. 50367) who operated a Women's Health practice in Memphis, within the Western District of Tennessee. The name of the practice was Poplar Avenue Clinic (PAC). KUMAR was a registered Medicare and Medicaid provider who utilized National Provider Identifier (NPI) 1932381530. PAC conducted business through NPI 1124588793. KUMAR specialized in gynecology and oncology.

2. Between September 12, 2019 and April 16, 2024, KUMAR was consistently the top-paid provider in Tennessee for Medicare and Medicaid for hysteroscopy biopsy services. KUMAR profited substantially from these billings to the Medicare and Medicaid programs.

3. To generate and retain these substantial profits, KUMAR engaged in a

series of crimes, frauds, and other acts that abused the trust of both the Medicare and Medicaid programs, and his patients. Specifically:

a. **Conducting unnecessary medical procedures**. KUMAR intended to and did conduct and repeat medically unnecessary hysteroscopy procedures on patients.

b. **Adulteration of single use hysteroscope cannulas**. KUMAR reused hysteroscope medical devices marked as "single use" on his patients without properly cleaning, disinfecting, and/or sterilizing the cannulas between use. The medical devices, which routinely contacted human tissue, discharge, and blood when inserted into the vagina and uterus, were not cleared by the United States Food and Drug Administration (FDA) to be reprocessed or reused. Nevertheless, across the relevant time period, KUMAR reused the devices as a routine business practice, often inserting the same device into more than one patient on the same business day under insanitary conditions. KUMAR billed health insurers including Medicare the value of the single use hysteroscope medical devices even when he was in fact reusing them. KUMAR increased his profits by not replacing the single use devices after every use.

c. **Misbranding of single use hysteroscope devices**. Even if KUMAR and his staff attempted to reprocess the single use devices specified herein, they failed to label the reprocessed devices accordingly, as is required by law. KUMAR failed to inform his patients that the single use devices were reprocessed.

d. **Adulteration of reusable hysteroscope devices**. KUMAR and his staff reused hysteroscopes that were cleared for reuse under strict reprocessing procedures to ensure that the devices were safe before reuse. However, KUMAR and his staff did not properly clean, sanitize, and/or sterilize the hysteroscope devices between uses and

instead maintained the devices under insanitary conditions. The reusable hysteroscope devices routinely contacted human tissue, discharge, and blood when inserted into the vagina and uterus. KUMAR and his staff thereby routinely reused the devices on patients which were held under insanitary conditions between patient use. KUMAR also maximized his profits by reusing hysteroscope devices that were not adequately reprocessed.

e. **Falsely billing health care insurance programs, including Medicare and Medicaid, for medical procedures that were medically unnecessary and/or used adulterated devices**. KUMAR routinely submitted claims to Medicare, Medicaid, and other health care benefits programs that were not medically necessary and/or were performed using devices that did not conform with FDA regulations.

BACKGROUND

A. HYSTEROSCOPY

4. A hysteroscopy is a gynecological medical procedure that allows a healthcare professional to examine the inside of the uterus using a medical device called a hysteroscope. The hysteroscope permits direct viewing of the cervical canal and the uterine cavity to diagnose and treat conditions such as abnormal uterine bleeding, fibroids, polyps, infertility and uterine septum, as well as to remove intrauterine devices (IUD). The hysteroscope can also be used in surgical procedures to take tissue samples of the endometrium. Because a hysteroscope enters the uterus, it must be sterile and/or correctly reprocessed to avoid the introduction of pathogenic microbes or cross-contamination between patients, which has a higher risk of infection.

B. THE USE, REGULATION, AND ADULTERATION OF MEDICAL DEVICES

5. The FDA regulates medical devices. The Federal Food, Drug, and Cosmetic Act (FDCA) defines a medical device, in pertinent part, as an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is intended for use in the diagnosis of disease or other condition, or in the cure, treatment, or prevention of a disease, in man or in animals, or intended to affect the structure or any function of the body of man or other animals. 21 U.S.C. § 321(h)(1).

6. Under the FDCA, a device is adulterated if, among other things, it was prepared, packaged, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health. 21 U.S.C. § 351(a)(2)(A).

7. A "single use device" means a device that is intended for one use, or on a single patient during a single procedure. 21 U.S.C. § 321(ll)(1). The term "reprocessed device" means an original device that has been previously used on a patient and has been subject to additional processing for the purpose of an additional, single use on a different patient. 21 U.S.C. § 321(ll)(2). Reprocessing is intended to remove blood, tissue, and other biological debris, and to inactivate infectious microbes so that devices are safe for the next patient. Proper reprocessing is labor-intensive and time-consuming, and generally requires a specific reprocessing regimen.

8. A reprocessed single use device is misbranded unless all labeling of the device prominently and conspicuously states, "Reprocessed device for single use" and identifies the person responsible for reprocessing. 21 U.S.C. § 352(v).

9. The FDCA makes it unlawful to do any act or cause any act to be done with respect to a medical device while the medical device was held for sale after shipment in interstate commerce, if such act results in the device being adulterated or misbranded. 21 U.S.C. § 331(k).

C. THE MEDICARE AND MEDICAID/TENNCARE PROGRAMS

10. Medicare is a federally funded health care program for those sixty-five (65) years old and older, as well as certain disabled persons. Medicare is funded by taxes on employees and premiums paid by Medicare recipients, also known as Medicare "beneficiaries." Medicare is a "health care benefit program." 18 U.S.C. § 24(b). Medicare is administered by the United States Department of Health and Human Service (HHS) through its component agency, the Centers for Medicare and Medicaid Services (CMS). CMS contracts with private health insurance companies known as Medicare Administrative Contractors (MAC) to process and pay Medicare claims.

11. Medicare is divided into a number of parts, providing coverage for various types of health care services: Part A for inpatient services (hospital and skilled nursing); Part B for physician and laboratory services; Part C for managed care plan where Medicare beneficiaries enroll with private insurance companies who receive a monthly, per beneficiary, fixed payment from HHS to receive inpatient, physician and laboratory services through contracted hospitals and providers; and Part D for prescription drug services.

12. For physicians, nurse practitioners, and diagnostic service providers, such as laboratory companies or other medical service providers (hereinafter collectively referred to as "Providers") to enroll in Medicare, they must first obtain a NPI number, which is assigned by the National Plan and Provider Enumeration System. Providers

cannot become a Medicare credentialed provider – and therefore cannot provide services to Medicare beneficiaries – without first obtaining an NPI. After obtaining an NPI, Providers must submit a provider enrollment application. If the application is approved, the Provider is Medicare-credentialed and is assigned a Medicare provider number, under which they can submit claims for medically necessary services rendered to Medicare beneficiaries and receive payment.

13. The Tennessee Medicaid Program (TennCare) is also a "health care benefit program." 18 U.S.C. § 24(b). TennCare provides benefits to Tennessee residents who meet certain eligibility requirements, including income requirements. TennCare is a jointly funded federal-state program.

14. Claims forms, called CMS 1500 forms, are submitted either electronically or by mail to the appropriate MAC. The claim forms include patient demographic information (e.g., name, address, Medicare beneficiary number, etc.) and a numeric code describing the services provided to the beneficiary.

15. Numeric codes used to describe the service provided are defined and listed in the Current Procedural Terminology (CPT) manual. The CPT manual is published by the American Medical Association (AMA).

16. CPT codes describe services provided to beneficiaries by Providers. Providers submit claims using a CPT code to describe the service provided to the patient. Medicare pays these claims based upon the representations made by the provider on the claim form. The CMS 1500 claim form, whether paper or electronic, contains certifications by the Provider that the services provided were medically indicated and necessary and that all claims are true, accurate, and complete.

17. In becoming an enrolled Medicare provider, Providers must agree to abide

by all Medicare laws, regulations, and program instructions. Providers must further certify that they will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare.

18. At all times relevant to this Indictment, health care benefits programs prohibited payment for items and services that were not "reasonable and necessary" for the diagnosis and treatment of an illness or injury.

19. For services provided in an office setting, the Medicare Part B payment to the provider includes reimbursement for the cost of supplies, equipment, and staff utilized when providing services.

COUNTS 1-4

(Enticement and Inducement to Travel to Engage in Illegal Sex Acts)

The Grand Jury further charges:

20. The allegations contained in paragraphs 1 through 19 of this Indictment are repeated and realleged as if fully set forth within.

21. From at least in and around September 2019 to in and around June 2024, in the Western District of Tennessee and elsewhere, the defendant,

SANJEEV KUMAR

did knowingly persuade, induce, entice, and coerce an individual to travel in interstate and foreign commerce to engage in sexual activity for which a person can be charged with a criminal offense, and attempted to do the same, to wit, KUMAR persuaded, induced, enticed, and coerced

Count #	Victim	Date Range
1	Victim-1	January 1, 2023 through March 7, 2023
2	Victim-2	November 11, 2019 through May 11, 2021
3	Victim-3	June 16, 2020 through November 15, 2022
4	Victim-4	April 11, 2022 through June 17, 2024

to travel to Memphis, Tennessee from another state on multiple occasions with the intention that KUMAR would engage in one or more sex acts with Victim-1, Victim-2, Victim-3 and Victim-4, in violation of Tennessee Code Ann. § 39-13-503.

All in violation of Title 18, United States Code, Sections 2422(a) and 2.

Adulterated and Misbranded Devices

A. LiNA OperaScope

22. During times material to this Indictment, the LiNA OperaScope was a medical device manufactured by LiNA Medical ApS (LiNA) outside the state of Tennessee.

23. In November 2017, LiNA submitted a premarket notification to the FDA, commonly known as a 510(k) premarket notification, in which it sought FDA clearance to market and sell the LiNA OperaScope, a hysteroscope, in interstate commerce, as a sterile, single use device, for use in visualization of the cervical canal and uterine cavity during diagnostic and therapeutic gynecological procedures.

24. During diagnostic and therapeutic procedures, such as hysteroscopy, the LiNA OperaScope regularly encountered vaginal secretions, mucus, tissue, blood, and other bodily fluids normally encountered in the vagina and uterus.

25. Components of the LiNA OperaScope were plastic and therefore could not be subjected to high temperature sterilization.

26. For these and other reasons, when LiNA submitted its 510(k) premarket notification for the LiNA OperaScope to the FDA for clearance to market in commerce, it did so only as a single use device. LiNA was required to demonstrate that its sterilization procedures were adequate to ensure human safety during the first and only

use of the device by the patient. Since the LiNA OperaScope was never designed or intended to be reused, the FDA was neither asked to, nor did it, review any proposed methods of reprocessing of the device for use on more than one patient, or any data supporting such reprocessing methods.

27. The instructions for use of the LiNA OperaScope, which were also submitted to the FDA as part of the 510(k) process and provided with the product, directly warned physicians that the device could only be used once, was intended to be sterile when used, and that the device could not be reprocessed or re-sterilized. For example, under the "WARNINGS" heading in the instructions for use, it is stated:

a. The LiNA OperaScope is provided STERILE via ethylene oxide (OperaScope) and radiation sterilization (Battery). Carefully inspect the packaging for any damage prior to use. Do NOT attempt to use the device if sterile barrier is damaged. Do NOT use past expiration date. Do NOT use if the device is exposed to nonsterile surfaces before procedure.

b. For single use only. Do NOT reuse, reprocess, or re-sterilize the LiNA OperaScope. Any reprocessing may impede the functions of this device. Reusing single use devices may also increase the risk of cross contamination. Attempts to clean the device results in risk of device malfunction and/or erroneous pathology specimen collection due to residual tissue in the LiNA OperaScope.

28. The "INSTRUCTION FOR USE" heading stated:

a. Carefully inspect the packaging for any damages prior to use. Do NOT attempt to use the device if the sterile barrier is damaged. Do not use past expiration date.

b. Using the sterile technique, remove the LiNA OperaScope from the sterilized blister.

29. In addition to the instructions for use, the LiNA OperaScope packaging included statements or depictions that the device was single use.

B. The Endosee PX Cannula

30. During times material to this Indictment, the Endosee PX Cannula was a medical device manufactured by Cooper Surgical, Inc. outside the state of Tennessee.

31. In April 2019, Cooper Surgical, Inc. submitted a premarket notification to the FDA, commonly known as a 510(k) premarket notification, in which it sought FDA clearance to market and sell the Endosee System, a hysteroscope, in interstate commerce. The Endosee System included the Endosee PX Cannula, a sterile, single use cannula, for use in viewing the adult cervical canal, uterine cavity, or female urinary tract, including the bladder, to perform diagnostic and therapeutic hysteroscopy or cystoscopy procedures in an operating room, outpatient, or office setting.

32. The Endosee PX Cannula was designed for a trained healthcare professional to insert into the vagina, past the cervix, and into the uterus of a patient, where the performance of certain gynecological procedures would then be performed. The device had a light source and camera at the distal end which were used for visualization and to capture image and video of the diagnostic area. By design, the device regularly contacted vaginal secretions, mucus, tissue, blood, and other bodily fluids normally encountered in the vagina and uterus.

33. An important additional feature of the Endosee PX Cannula was that it had a hollow interior cavity which ran from the end of the device all the way to the tip. This hollow interior allowed for the healthcare professional to, for example, introduce sterile

instruments into the uterus of a patient to remove uterine tissue through the device for laboratory analysis.

34. While the foregoing feature of the Endosee PX Cannula provided advantages during treatment, it also created areas of the device that could collect mucus, tissue, blood, and other bodily fluids which could not be adequately reached for proper sterilization. Moreover, since components of the device were plastic, it could not be subjected to high temperature sterilization.

35. For these and other reasons, when Cooper Surgical, Inc. submitted its 510(k) premarket notification for the Endosee PX Cannula to the FDA for clearance to market in commerce, it did so only as a single use device. Cooper Surgical, Inc. was required to demonstrate that its sterilization procedures were adequate to ensure human safety during the first and only use of the device by the patient. Since the Endosee PX Cannula was never designed or intended to be reused, the FDA was neither asked to, nor did it, review any proposed methods of reprocessing of the device for use on more than one patient, or any data supporting such reprocessing methods.

36. The instructions for use of the Endosee System, which were also submitted to the FDA as part of the 510(k) process and provided with the product, directly warned physicians that the cannula could only be used once, and that the cannula could not be reprocessed or re-sterilized.

37. The “Product Description” heading in the instructions for use stated, among other things, “2.3 Sterile, Single-Use Cannula – Do not use the Cannula if the package has been damaged or the expiration date on the label has passed. The Cannula is single-use only. Do not re-use or re-sterilize the Cannula.”

38. The "Warnings and Precautions" heading stated: "3.4 Inspection, Use and Disposal – Do not use the Cannula if the package has been damaged or the expiration date on the label has passed. The Cannula is single-use only. Do not re-use or re-sterilize the Cannula. The Cannula must be disposed of as biohazardous waste according to the safety guidelines of user facility/institution ... No portion of the Endosee Advance System should be opened for cleaning or disinfecting."

39. The "Device Maintenance" heading stated: "5.3 Disposable Cannula Handling/Care – The Cannula is provided sterile and is a single-use[] item. As such, no formal cleaning or disinfection procedures apply to the Cannula."

40. In addition to the instructions for use, the Endosee PX Cannula packaging included statements or depictions that the device was single use.

C. Hystero-V Hysteroscope

41. During times material to this Indictment, the Hystero-V Hysteroscope was a medical device manufactured by UroViu Corporation outside the state of Tennessee.

42. In October 2021, Hysterovue, Inc., on behalf of UroViu Corporation, submitted a premarket notification to the FDA, commonly known as a 510(k) premarket notification, in which it sought FDA clearance to market and sell the Hystero-V Hysteroscope, a hysteroscope, in interstate commerce, which consisted of a sterile, single use disposable cannula, intended to be used to permit viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic procedures and to obtain an endometrial tissue sample (biopsy) in an outpatient or in an office setting. The sample is used for cytologic and histologic diagnosis.

43. During diagnostic and therapeutical gynecological procedures, such as hysteroscopy, the Hystero-V Hysteroscope's single use cannulas regularly encountered

vaginal secretions, mucus, tissue, blood, and other bodily fluids normally encountered in the vagina and uterus.

44. Components of the Hystero-V Hysteroscope cannula were made of plastic and therefore could not be subjected to high temperature sterilization.

45. For these and other reasons, when Hysterovue, Inc. submitted its 510(k) premarket notification for the Hystero-V Hysteroscope to the FDA for clearance to market in commerce, it did so with the use of a single use cannula device. Hysterovue, Inc. was required to demonstrate that its sterilization procedures were adequate to ensure human safety during the first and only use of the device by the patient. Since the Hystero-V Hysteroscope cannula was never designed or intended to be reused, the FDA was neither asked to, nor did it, review any proposed methods of reprocessing of the device for use on more than one patient, or any data supporting such reprocessing methods.

46. The instructions for use of the Hystero-V Hysteroscope, which was also submitted to the FDA as part of the 510(k) process directly warned physicians that the cannula could only be used once, was intended to be sterile when used, and that the cannula could not be reprocessed or re-sterilized.

47. The “General Warnings” heading in the instructions for use stated:

a. Do not use the cannula if the sterile barrier is damaged or if the expiration date (use by date) printed on the label has passed.

b. The Hystero-V Hysteroscope cannula must be disposed of as biohazardous waste according to the safety guidelines of the user facility/institution and must be disposed of in accordance with local and/or state laws governing the collection of biohazardous medical devices with electronic components.

48. The “Cautions” heading stated: “[f]or single patient use only. Do not reuse, reprocess, or attempt to re-sterilize the cannula.”

49. The “Preparation for Use” heading stated:

a. Each cannula comes sealed in a pouch and has been sterilized using Ethylene Oxide (ETO).

i. Do not use, if sterile barrier is damaged.

ii. The expiration date (use by date) is shown on the package labeling. Check that the expiration date has not passed before use.

50. The “Description of Components” heading stated: “Sterile, Single-use Cannula – the disposable single-use cannula contains a miniature CMOS camera and light-emitting diodes (LED) illumination module at the tip.”

51. The “Prior to the Examination” heading stated: “Open the pouch containing the sterile cannula and remove the cannula while maintaining sterile conditions.”

52. The “Removal of the System” heading stated: “The Hystero-V Hysteroscope cannula must be disposed of as biohazardous waste according to the safety guidelines of user facility/institution and must be disposed of in accordance with local and/or state laws governing the collection of biohazardous medical devices with electronic components.”

53. In addition to the instructions for use, the Hystero-V Hysteroscope packaging included statements or depictions that the device was single use and not to be resterilized.

D. LiNA Operascope Biopsy Forceps

54. During times material to this Indictment, the LiNA OperaScope Biopsy Forceps was a medical device manufactured by LiNA Medical ApS (LiNA) outside the state of Tennessee. The LiNA OperaScope Biopsy Forceps are intended for use in hysteroscopic and female cystoscopy procedures to obtain tissue samples for examination of tissue from the uterine cavity of urinary bladder.

55. The instructions for use of the LiNA OperaScope Biopsy Forceps, which were provided with the product, directly warned physicians that the forceps could only be used once, were intended to be sterile when used, and that the forceps could not be reprocessed or re-sterilized. For example, under the heading "WARNINGS" the instructions stated:

a. The Forceps are provided STERILE via ethylene oxide sterilization.

b. Carefully inspect the packaging for any damage prior to use. Do NOT use the device if the sterile barrier is damaged.

c. Do NOT use the device if exposed to non-sterile surfaces before procedure.

d. Do NOT use if past expiration date or if missing expiry date.

e. For single use only. Do NOT reuse, reprocess or re-sterilize the Forceps. Any reprocessing may impede the functions of this device. Reusing single use devices may also increase the risk of cross contamination. Attempts to clean the device results in risk of device malfunction and/or erroneous pathology specimen collection due to residual tissue in the Forceps.

E. CooperSurgical Disposable Alligator Grasper Forceps

56. During times material to this Indictment, the CooperSurgical Disposable Alligator Grasper Forceps was a medical device manufactured by Zhuji Pengtian Medical Instrument Co., Ltd outside the state of Tennessee and distributed by CooperSurgical. The CooperSurgical Endosee Disposable Alligator Grasper Forceps are indicated for use to grasp and manipulate tissue during various endoscopic surgical procedures.

57. The instructions for use of the Disposable Alligator Grasper Forceps directly warned physicians that the device could only be used once, were intended to be sterile when used, and that the device could not be reprocessed or resterlized. For example, under the heading “WARNINGS and PRECAUTIONS” the instructions stated:

a. Do not use if packaging sterile barrier is damaged.

b. Do not use if package has exceeded the expiration date.

c. For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or crossinfection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Dispose of in accordance with all applicable Federal, State and local Medical/Hazardous waste practices.

d. Disposable Alligator Grasper is a single use product, one per patient, no cross-use between patients.

F. Purchase History of Single Use Devices

58. Between in and around September 2019 and in and around April 2024, KUMAR obtained and caused to be obtained approximately the following number of the

aforementioned single use hysteroscopy medical devices from outside the state of Tennessee for use in hysteroscopy procedures. Many of the hysteroscopy procedures during this time were accomplished by reusing the single-use medical devices on multiple patients.

Medical Device	Quantity Obtained	Cost/Unit
LiNA Operascope	12	$253.00
Endosee PX Cannula	85	$175.00
Hystero-V Hysteroscope	32	$105.00
LiNA Operascope Biopsy Forceps	6	$49.00
CooperSurgical Disposable Alligator Grasper Forceps	20	$50.00

G. Single Use Device Adulteration

59. KUMAR directed his staff to prepare the aforementioned single use medical devices for reuse by soaking them in a plastic container of cleaning agents in the exam rooms. He further directed staff to change out the cleaning agent every two weeks, approximately. At times, multiple single use medical devices were placed in the same plastic container to soak together in the cleaning agent. Before reuse, the medical devices would be removed from the cleaning agent and rinsed under tap water. These efforts did not adequately reprocess the devices and caused them to be held in insanitary conditions whereby they may have been contaminated with filth, or whereby they may have been rendered injurious to health before use on future patients.

60. KUMAR and others under his supervision at PAC concealed and omitted from patients, insurers including Medicare and TennCare, and others the fact that they were reusing the aforementioned single use devices which were adulterated. In this

way, KUMAR failed to obtain the informed consent of his patients in carrying out hysteroscopy procedures and acted with intent to defraud and mislead.

61. KUMAR boosted his profits by subjecting patients to the use of adulterated medical devices rather than using a new, sterile device for every procedure.

COUNTS 5 – 9
(Adulteration of Single Use Devices)

The Grand Jury further charges:

62. The allegations contained in paragraphs 1 through 19 and 21 through 61 of this Indictment are repeated and realleged as if fully set forth within.

63. From at least in and around September 2019 to in and around April 2024, in the Western District of Tennessee and elsewhere, the defendant,

SANJEEV KUMAR

with intent to defraud and mislead, did or caused acts to be done with respect to medical devices, specifically, the single use devices set out in the table below, while the medical devices were held for sale after shipment in interstate commerce, that resulted in the medical devices being adulterated.

Count #	Device Name
5	Endosee PX Cannula
6	LiNA OperaScope
7	Hystero-V Hysteroscope
8	LiNA Operascope Biopsy Forceps
9	CooperSurgical Disposable Alligator Grasper Forceps

All in violation of Title 21, United States Code, sections 331(k), 333(a)(1), 333(a)(2), and 351(a)(2)(A).

COUNTS 10 - 12
(Misbranding of Reprocessed Single Use Devices)

64. The allegations contained in paragraphs 1 through 19 and 21 through 61 of this Indictment are repeated and realleged as if fully set forth within.

65. From at least in and around September 2019 to in and around April 2024, in the Western District of Tennessee and elsewhere, the defendant,

SANJEEV KUMAR

with intent to defraud and mislead, did or caused acts to be done with respect to medical devices, specifically, the single use devices set out in the table below, while the medical devices were held for sale after shipment in interstate commerce, which resulted in the devices being misbranded within the meaning of 21 U.S.C. § 352(v).

Count #	Device Name
10	Endosee PX Cannula
11	LiNA OperaScope
12	Hystero-V Hysteroscope

All in violation of Title 21, United States Code, sections 331(k), 333(a)(1), 333(a)(2), and 352(v).

H. Olympus HYF-XP Hysterofiberscope

66. During times material to this Indictment, the Olympus HYF-P Hysterofiberscope (later referred to as the Olympus HYF-XP Hysterofiberscope) was a medical device manufactured by Olympus Medical Systems Corp. (Olympus) outside the state of Tennessee.

67. In 1989, Olympus submitted a premarket notification to the FDA, commonly known as a 510(k) premarket notification, in which it sought FDA clearance

to market and sell the HYF-XP Hysterofiberscope in interstate commerce, for use in visualization of the cervical canal and uterine cavity during diagnostic and therapeutic gynecological procedures.

68. During diagnostic and therapeutic procedures, such as hysteroscopy, the HYF-XP Hysterofiberscope regularly encountered vaginal secretions, mucus, tissue, blood, and other bodily fluids normally encountered in the vagina and uterus. The device requires adequate reprocessing between each use to avoid risk of infection.

COUNT 13

(Adulteration of Hysteroscopes Cleared for Reprocessing)

The Grand Jury further charges:

69. The allegations contained in paragraphs 1 through 19, 61, and 66 through 68 of this Indictment are repeated and realleged as if fully set forth within.

70. From at least in and around October 2019 to in and around April of 2024, in the Western District of Tennessee and elsewhere, the defendant,

SANJEEV KUMAR

with intent to defraud and mislead, did or caused acts to be done with respect to medical devices, specifically, Olympus HYF-XP Hysterofiberscopes, while the medical devices were held for sale after shipment in interstate commerce, that resulted in the medical devices being adulterated.

All in violation of Title 21, United States Code, sections 331(k), 333(a)(1), 333(a)(2), and 351(a)(2)(A).

Health Care Fraud

A. The Scheme

71. Beginning not later than September 2019 and continuing thereafter

through April 16, 2024, in the Western District of Tennessee and elsewhere, KUMAR devised and participated in a scheme and artifice to defraud health insurance benefit programs, including Medicare and Medicaid. It was the purpose of the scheme and artifice for KUMAR to unlawfully enrich himself through the submission of false and fraudulent claims for services that were: (a) not medically necessary and, therefore, not eligible for reimbursement; (b) performed without the informed consent of the patient; (c) based upon fraudulent and falsified patient symptoms and diagnoses; and (d) performed with adulterated devices.

72. In perpetrating his scheme, KUMAR employed several types of false and fraudulent claims. KUMAR and/or his clinical staff would routinely falsely claim that a patient sought out, and authorized, a particular gynecological procedure; routinely record in a patient's medical record that a patient reported symptoms or complaints from which she did not actually suffer nor relay to KUMAR and/or his clinical staff; and routinely fail to obtain informed consent for the procedures performed. Examples of KUMAR's overt acts in furtherance of the scheme and artifice include the following:

a. Victim-1 presented to KUMAR with complaints of abdominal pain. Victim-1 had not yet gone through menopause and was still having regular periods. However, KUMAR documented that the patient presented for post-menopausal bleeding. Victim-1 underwent hysteroscopies on 1/2/23, 1/30/23, 2/13/23, and 3/7/23. The procedures performed on 1/30/23, 2/13/23, and 3/7/23 were not medically indicated.

b. Victim-3 presented to KUMAR following a diagnosis of Vulvar Paget's disease. The patient was post-menopausal and had not experience any post-menopausal bleeding. However, KUMAR documented in Victim-3's

record that she was experiencing post-menopausal bleeding. Victim-3 underwent eight hysteroscopy procedures, at least four of which (dates of service of 1/5/21, 4/8/21, 10/26/21, and 11/15/22) were not medically indicated.

c. Victim-4 presented to KUMAR for pain and cysts on her ovaries. KUMAR performed six hysteroscopies on Victim-4 during the relevant time period, at least three of which (dates of service of 5/5/22, 5/19/22, and 2/6/24) were not medically necessary.

d. Victim-5 presented to PAC to receive a birth control prescription. Victim-5 was 14-years-old and this was her first gynecological appointment. At KUMAR'S direction, a PAC staff member performed a hysteroscopy with endometrial biopsy on Victim-5 that was not medically necessary.

e. Victim-6 presented to PAC with reports of abnormal bleeding. At KUMAR'S direction, Victim-6 underwent at least seven hysteroscopies, at least three of which (dates of service 4/19/21, 7/19/21, and 12/7/21) were not medically necessary.

f. Victim-7 presented to PAC with complaints of a vulvar cyst. At KUMAR'S direction, Victim-7 underwent five hysteroscopies (dates of service 2/3/22, 7/28/22, 9/7/22, 11/5/22, and 1/18/23), all of which were medically unnecessary.

g. Victim-8 presented to KUMAR for routine gynecologic care. She was not post-menopausal and was still experiencing regular periods. However, KUMAR documented that she was referred to him for post-menopausal bleeding. At KUMAR'S direction, Victim-8 underwent at least fourteen

hysteroscopies, at least ten of which (dates of service 5/21/22, 6/25/22, 9/24/22, 10/8/22, 12/10/22, 2/10/23, 3/10/23, 410/23, 11/6/23, and 12/4/23) were medically unnecessary.

h. Victim-9 presented to PAC following an abnormal pap smear. At KUMAR'S direction, Victim-9 underwent five hysteroscopies (dates of service 6/9/20, 10/28/20, 3/20/21, 4/15/21, and 4/30/21) that were medically unnecessary.

i. Victim-10 presented to KUMAR for fertility issues. KUMAR repeatedly documented in Victim-10's medical record that she was experiencing abnormal bleeding with blood clots, despite her not reporting this symptom. KUMAR performed six hysteroscopies with endometrial biopsies on Victim-10, four of which (dates of service 10/16/21, 4/30/22, 3/4/23, and 5/6/23) were medically unnecessary. PAC also billed TennCare for another hysteroscopy supposedly conducted on 9/19/22, and sent a sample to a pathology lab, but no hysteroscopy is documented on that day in Victim-10's medical record.

73. It was part of the scheme and artifice to defraud that KUMAR would instruct his clinical staff that every new patient be treated as critical regardless of age, complaint, reason for referral, or clinical presentation. This meant that each patient would undergo a pap smear, transvaginal ultrasound, and hysteroscopy with endometrial biopsy procedure during their initial new patient visit.

74. It was further part of the scheme and artifice to defraud that KUMAR would instruct his clinical staff to reprocess single use medical devices and continue to use them on patients past the initial single use. At KUMAR's instruction, his staff would

reuse single use cannulas until they broke or became too obstructed to observe the patient's uterine cavity. KUMAR would further instruct his staff to inadequately reprocess hysteroscope devices and reuse them without adequate processing.

75. It was further part of the scheme and artifice to defraud that KUMAR would hire clinical staff who were inexperienced and/or new to gynecological medicine so that he could train them to perform and assist in the performance of procedures that were medically unnecessary and/or conducted with adulterated devices. KUMAR hired inexperienced staff members so they would be less likely to recognize that these procedures were not within the applicable standard of practice, were in fact medically unnecessary, and potentially harmful to the patients.

76. It was further part of the scheme and artifice to defraud that KUMAR would document, and cause others known and unknown to the Grand Jury to document, in patient files inconsistent, false, and rote information to create documentation supporting the reimbursement claims submitted to Medicare, Medicaid, and other insurance benefit programs.

77. From on or about September 19, 2019, through on or about April 16, 2024, KUMAR submitted and caused to be submitted thousands of claims to health care benefit programs for hysteroscopy with endometrial biopsy procedures.

The Offenses

COUNTS 14 – 22
(Health Care Fraud)

The Grand Jury further charges:

78. The allegations contained in paragraphs 1 through 19, 22 through 61, 66 through 68, and 71 through 77 of this Indictment are repeated and realleged as if fully

set forth within.

79. Beginning at a time unknown, but no later than September of 2019, and continuing to April of 2024, in the Western District of Tennessee and elsewhere, the defendant,

SANJEEV KUMAR

did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud a health care benefit program affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is Medicare, Medicaid, and others, and to obtain, by means materially false and fraudulent pretenses, representations, promises, and money and property owned by and under the custody of Medicare, Medicaid, and others, in connection with the delivery of and payment for health care benefits, items, and services, to wit: KUMAR submitted and caused to be submitted, and attempted to do so, claims for reimbursement for hysteroscopy with endometrial biopsy procedures to health care benefit programs that were false and fraudulent, as follows:

Count	Date of Service	Health Care Benefit Program	Patient	Approximate Amount Billed	False/Fraudulent Representation
14	1/30/23 2/13/23 3/7/23	Medicare Medicare Medicare	Victim-1 Victim-1 Victim-1	$2,515.00 $2,515.00 $2,515.00	Fraudulent representation of patient complaints; not medically necessary
15	1/5/21 4/8/21 10/26/21 11/10/22	Medicare Medicare Medicare Medicare	Victim-3 Victim-3 Victim-3 Victim-3	$2,515.00 $2,515.00 $2,515.00 $2,515.00	Fraudulent representation of patient complaints; not medically necessary
16	5/5/22 5/19/22 2/6/24	Medicare Medicare Medicare	Victim-4 Victim-4 Victim-4	$2,515.00 $2,515.00 $2,515.00	Not medically necessary
17	8/26/21	Medicaid	Victim-5	$2,515.00	Not medically necessary

18	4/19/21 4/19/21 7/19/21 7/19/21 12/7/21 12/7/21	Medicare Medicaid Medicare Medicaid Medicare Medicaid	Victim-6 Victim-6 Victim-6 Victim-6 Victim-6 Victim-6	$2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00	Not medically necessary
19	2/3/22 7/28/22 9/7/22 11/5/22	Medicaid Medicaid Medicaid Medicaid	Victim-7 Victim-7 Victim-7 Victim-7	$2,515.00 $2,515.00 $2,515.00 $2,515.00	Not medically necessary
20	5/21/22 5/21/22 5/21/22 6/25/22 6/25/22 9/24/22 10/8/22 12/10/22 2/10/23 3/10/23 4/10/23	Medicare Medicare* Medicaid Medicare Medicaid Medicaid Medicaid Medicaid Medicaid Medicaid Medicaid	Victim-8 Victim-8 Victim-8 Victim-8 Victim-8 Victim-8 Victim-8 Victim-8 Victim-8 Victim-8 Victim-8	$2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00	Fraudulent representation of patient complaints; not medically necessary *second submission of claim
21	6/9/20 10/28/20 3/20/21 4/15/21 4/30/21	Medicaid Medicaid Medicaid Medicaid Medicaid	Victim-9 Victim-9 Victim-9 Victim-9 Victim-9	$2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00	Not medically necessary
22	10/16/21 4/30/22 9/19/22 3/4/23 5/6/23	Medicaid Medicaid Medicaid^ Medicaid Medicaid	Victim-10 Victim-10 Victim-10 Victim-10 Victim-10	$2,515.00 $2,515.00 $2,515.00 $2,515.00 $2,515.00	Fraudulent representation of patient complaints; not medically necessary ^procedure not performed

All in violation of Title 18, United States Code, Section 1347.

COUNT 23
(Health Care Fraud)

The Grand Jury further charges:

80. The allegations contained in paragraphs 1 through 19, 22 through 61, 66 through 68, and 71 through 77 of this Indictment are repeated and realleged as if fully set forth within.

81. Beginning at a time unknown, but no later than September of 2019, and

continuing to April of 2024, in the Western District of Tennessee and elsewhere, the defendant,

SANJEEV KUMAR

did knowingly and willfully execute, and attempt to execute, a scheme and artifice to defraud a health care benefit program affecting commerce, as defined in Title 18, United States Code, Section 24(b), that is Medicare, Medicaid, and others, and to obtain, by means materially false and fraudulent pretenses, representations, promises, and money and property owned by and under the custody of Medicare, Medicaid, and others, in connection with the delivery of and payment for health care benefits, items, and services, to wit: KUMAR submitted and caused to be submitted, and attempted to do so, claims for reimbursement for hysteroscopy services to health care benefit programs that were false and fraudulent, in that he falsely attested that he followed all pertinent rules and regulations in providing these services, including that the devices used during the procedures comported with all applicable regulations and were approved for use in patient care.

All in violation of Title 18, United States Code, Section 1347.

NOTICE OF FORFEITURE ALLEGATIONS

82. The allegations of this Indictment are re-alleged and by this reference fully incorporated herein for the purpose of alleging forfeiture to the United States of America of certain property in which the defendant, **SANJEEV KUMAR**, has an interest.

83. Upon conviction of a violation of Title 18, United States Code, Section 1347, or Title 21 United States Code, Section 331, as alleged in this Indictment, the defendant **SANJEEV KUMAR**, shall forfeit to the United States any property, real or

personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offense(s), in violation of 18 U.S.C. § 1347 or 21 U.S.C. § 331(k), pursuant to 18 U.S.C. § 982(a)(7) and the provisions of 21 U.S.C. § 853.

84. If any of the property described above as being subject to forfeiture, as a result of any act or omission of any defendant:

i. cannot be located upon the exercise of due diligence;

ii. has been transferred or sold to, or deposited with, a third person;

iii. has been placed beyond the jurisdiction of this Court;

iv. has been substantially diminished in value; or

v. has been commingled with other property that cannot be divided without difficulty,

it is the intent of the United States, pursuant to Title 21, United States Code, Section 853(p), as incorporated by reference in Title 18, United States Code, Section 982(b)(1), to seek forfeiture of any other property of said defendant up to the value of the forfeitable property.

A TRUE BILL:

_____

FOREPERSON

DATE: February 27, 2025

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REAGAN TAYLOR FONDREN
ACTING UNITED STATES ATTORNEY